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EXAMINER	
FERTIG, BRIAN E	
ART UNIT	PAPER NUMBER
3694	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,878	MILOV, DAVID E.	
	Examiner	Art Unit	
	BRIAN FERTIG	3694	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicant's filing of 9/17/2008. Claims 1-21 are pending and examiner below.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-11 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims recite material that, when given its broadest reasonable interpretation, embody programs and data structures, per se. Programs and data structures are non-statutory subject matter when not properly embodied (see MPEP § 2106.1). Further, these claims recite references to non-functional descriptive material. Examples include electronic documents and evidence levels. As claimed, this data is neither properly embodied (see above) nor does it impart functionality when employed as a computer component. (see MPEP § 2106.1). Please see further comments directed to Applicant's amendment below.

Examination Note

3. Examiner notes that a number of Applicant's amended limitations are directed to further limiting protocol information and evidence level, suggesting Applicant wishes to differentiate the present invention from the prior art based on characteristics of the data. As claimed, protocol information and evidence level are non-functional descriptive material in so far as the claims do not recite limitations by which the characteristics of

the protocol information and evidence level data cause a functional or structural difference in the invention. Examiner respectfully suggests the inventions that depend on the characteristics of the data are often more easily recited as processes or as an apparatus with functional language. Such recitations allow the claim the potential to demonstrate a functional dependence on the characteristics of the claimed data, for example, through the positive recitation of a processing step that is dependent on the particular data.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,307,262 to Ertel (Ertel).

With respect to claim 1

Ertel teaches:

A computer implemented medical database comprising:

a document management system software module (i.e. see col 7, lines 55-66 in combination with col 8, lines 45-61) configured to receive and store a plurality of medical documents (i.e. cases), each of said plurality of documents having

a) protocol information associated therewith (i.e. patient demographic, clinical, diagnostic, and procedure codes, see col 8, lines 45-52, col 9, lines 25-40), the protocol information including at least one of a diagnosis protocol including a list of symptom associated with a medical diagnosis and a treatment protocol including one or more medical procedures to be performed (i.e. diagnosis indicator, see col 8, lines 45-61); and

b) an evidence level associated with each of said plurality of documents (i.e. information pertaining to data quality, see col 16, lines 20-27), said evidence level being a rating metric indicating a confidence level associated with the protocol information, the confidence level based on at least one of a peer review and empirical information (see col 12, lines 5-20 and col 28, lines 35-50)

With respect to claim 2

Ertel teaches:

A computer implemented medical database according to claim 1 (see rejection of claim 1 above), wherein the evidence level is based upon a plurality of factors, said factors including one or more of the following: controlled study data, cross-over trial data, and placebo study data, and common practice data. (i.e. disallowed value or error condition, non-compliance with explicit requirements or published guidelines, see col 11, line 45-col 12, line 20)

With respect to claim 3

Ertel teaches:

A computer implemented medical database according to claim 2 (see rejection of claim 2 above), wherein: each evidence level is determined by a consensus among peers (see col 12, lines 5-20, note that explicit requirements and published guidelines are determined by a consensus among peers. See also col col 10, lines 46-55, note that additional evidence level indicators will be determined by further review of certain cases By claims payees and peer review organizations).

With respect to claim 4

Ertel teaches:

A computer implemented medical database according to claim 3 (see rejection of claim 3 above), wherein: each evidence level equals a percentage from 0% to 100% (see col 14, lines 5-54, note that reports are generated containing percentages and each case includes a data quality status).

With respect to claim 5

Ertel teaches:

A computer implemented medical database according to claim 4 (see rejection of claim 4 above), further including links to said protocol information associated with each of said plurality of documents (see col 8, lines 45-52, note that because the cases are stored with their protocol information in a data base all of which are retrieved together for review, it is implicit that this information is linked).

With respect to claim 6

Ertel teaches:

A computer implemented medical database according to claim 5 (see rejection of claim 5 above), further including one or more concept unique identifiers associated with each of said plurality of documents (i.e. diagnoses and procedure codes, see col 8, lines 45-52, col 9, lines 25-40).

With respect to claim 7

Ertel teaches:

A computer implemented medical database according to claim 6 (see rejection of claim 6 above), further including one or more evaluation and management codes associated with each of said plurality of documents (i.e. Control information, see col 8, lines 45-52, col 9, lines 25-40)

With respect to claim 8

Ertel teaches:

A computer implemented medical database according to claim 7 (see rejection of claim 7 above), further including:

a computer-implemented user interface configured to access the computer implemented medical database (i.e. system utility/utility program, see col 9, line 41-col 10, line 12, col 25, lines 55-68, col 27, lines 18-22), and

computer program coding for each of said plurality of documents, said computer program coding being configured to enable presentation of

the document using the computer implemented user interface (see, col 27, lines 18-22, note that the interface allows the documents to be printed).

With respect to claim 9

Ertel teaches:

A computer implemented medical database according to claim 8 (see rejection of claim 8 above), further including: one or more templates, each of said one or more templates being configured for entry of the each of said plurality of medical documents, concept unique identifiers, and evaluation and management codes in the database (i.e. worksheets, see col 39, lines 45-60 and Tables 1A and B).

With respect to claim 10

Ertel teaches:

A computer implemented medical database according to claim 9 (see rejection of claim 9 above), further including: a document type identifier associated with each of said plurality of medical documents (see, col 8, lines 62-68, note that to prevent duplicate entry of a patient admission, it is implicit that a document type identifier be associated).

With respect to claim 11

Ertel teaches:

A computer implemented medical database according to claim 10 (see rejection of claim 10 above), wherein the documents type identifier includes an indication of age for an intended reader of one or more of said plurality of documents (i.e Adm date, dis date, report date, see Table 1A).

With respect to claim 12

Ertel teaches:

A method for creating a medical database, said method comprising steps of:

assigning a topic (i.e. entering patient information, see col 8, lines 45-52), the topic including at least one of a diagnosis protocol including a list of syrnptom associated with a medical diagnosis and a treatment protocol including one or more medical procedures to be performed (see col 8, lines 45-52, note diagnosis and procedure codes);

receiving a document on the topic (i.e. compiling case report including diagnosis, etc, see col 8, lines 45-52);

submitting the document to peers for review and assignment of an evidence level (i.e. peer review, see col 10, lines 46-55) said evidence level indicating a confidence level associated with the received document, the confidence level based on at least one of a peer review and empirical information related to the medical diagnosis or medical procedure (i.e. information pertaining to data quality, see col 16, lines 20-27, note also the peer review teachings of col 10, line 46-55 and the review teachings of col 12, lines 5-20 and col 28, lines 35-50); and

entering the document and the assigned evidence level for the document in a computer accessible database (see col 8, lines 45-52 and col 12, lines 4-20, note the quality messages are stored).

With respect to claim 13

Ertel teaches:

> The method according to claim 12 (see rejection of claim 12 above), said method further wherein the assigned evidence level is based upon a plurality of factors, said factors including one or more of the following: controlled study data, cross-over trial data, and placebo study data, and common practice data (i.e. disallowed value or error condition, non-compliance with explicit requirements or published guidelines, see col 11, line 45-col 12, line 20).

With respect to claim 14

Ertel teaches:

> The method according to claim 13 (see rejection of claim 13 above), wherein the assigned evidence level is determined by a consensus among peers (see col 12, lines 5-20, note that explicit requirements and published guidelines are determined by a consensus among peers. See also col col 10, lines 46-55, note that additional evidence level indicators will be determined by further review of certain cases By claims payees and peer review organizations).

With respect to claim 15

Ertel teaches:

> The method according to claim 14 (see rejection of claim 14 above), said method further including steps of assigning a concept unique identifier with the document and entering the assigned concept unique identifier in the database (i.e. diagnoses and procedure codes, see col 8, lines 45-52, col 9, lines 25-40).

With respect to claim 16

Ertel teaches:

The method according to claim 15 (see rejection of claim 15 above), said method further including steps of assigning a evaluation and management code with the document and entering the assigned evaluation and management code in the database (i.e. Control information, see col 8, lines 45-52, col 9, lines 25-40).

With respect to claim 17

Ertel teaches:

The method according to claim 16 (see rejection of claim 16 above), said method further including steps of assigning a critical data element with the document and entering the assigned critical data element in the database (i.e. DRG assignment information, see col 8, lines 53-61).

With respect to claim 18

Ertel teaches:

The method according to claim 17 (see rejection of claim 17 above), said method further including steps encoding the document into a format compatible with a user interface (see, col 27, lines 18-22, note the document is printed).

With respect to claim 19

Ertel teaches:

A computer implemented medical database comprising a database management system for storing a plurality of medical documents (i.e. database), associated protocol information (i.e. patient demographic, clinical, diagnostic, and procedure codes), and associated evidence levels (i.e. information pertaining to data

quality), each of said plurality of documents having protocol information associated therewith, and each of said plurality of documents having an evidence level associated therewith (see col 8, lines 45-52, col 9, lines 25-40 and col 16, lines 20-27, note that because the cases data is stored in a data base and all associated with a case) the protocol information including at least one of a diagnosis protocol including a list of symptom associated with a medical diagnosis and a treatment protocol including one or more medical procedures to be performed, and each of said plurality of documents having an evidence level associated therewith, said evidence level being a rating metric indicating a confidence level associated with the protocol information, the confidence level based on at least one of a peer review and empirical information (note that the database management systems is recited as being 'for storing' the recited subject matter. Such claim language requires that the prior art be only capable of performing the claimed intended use. The database of Ertel demonstrates such capability by the storage of various types of information.)

With respect to claim 20

Ertel teaches:

A computer implemented medical database according to claim 19 (see rejection of claim 19 above), further comprising a template for entering the plurality of medical documents, associated protocol information, and associated evidence levels into the database (i.e. worksheets, see col 39, lines 45-60 and Tables 1A and B).

With respect to claim 21

Ertel teaches:

A computer implemented document management system, comprising:

a document management software module configured to receive and store a plurality of medical documents (see col 7, lines 35-66 in combination with col 8, lines 45-61), each of said plurality of documents including protocol information associated therewith, the protocol information including at least one of a diagnosis protocol including a list of symptom associated with a medical diagnosis and a treatment protocol including one or more medical procedures to be performed (see col 8, lines 45-61, note diagnosis and procedure codes);

and

an evidence level generation software module configured to generate an evidence level for the protocol information each of said plurality of documents (i.e. automated data quality edit checking, see col 10, lines 15-64),

wherein generating an evidence level includes at least one of

transmitting a medical document including the protocol information to a peer review group, receiving a peer review, and setting an evidence level based on the peer review (see col 10, lines 30-64, note peer review

organizations interested in data quality problems, see also col 28, lines 35-50),

determining whether the protocol information has been the subject of on or more empirical studies and setting an evidence level based on the results of the one or more empirical studies (see col 11, line 45-col 12, line 20, note that data quality is based, in part, on non-compliance with published guidelines).

Response to Arguments

6. Applicant's arguments, with respect to Priority have been fully considered and are persuasive. The comments with respect to Priority in the Office Action of 3/18/2008 has been withdrawn.

7. Applicant's amendment to correct the deficiencies under 35 USC 112 , second paragraph, related to 'means for' language is acknowledged and the related rejection is withdrawn.

8. Applicant's arguments filed 9/17/2008 with respect to 35 USC 101 and 35 USC 102 have been fully considered but they are not persuasive. With respect to Applicant's argument that the introduction of a software module into the body of claim 1 resolves that rejection under 35 USC 101, Examiner respectfully disagree. Claim 1 is directed to a computer implemented medical database. The introduction of a software module, still caused the claims to be directed to software per se. According to MPEP § 2106.01, a

claimed computer-readable medium encoded with a data structure (or software) defines structural and functional interrelationships between the data structure and the computer software and hardware components which permit the data structure's functionality to be realized, and is thus statutory. To the extent supported by Applicant's disclosure, Examiner respectfully suggests amending the preamble of claim 1 so as to embody the database on a computer readable medium, executable by the computer system.

9. With respect to Applicant's arguments that Ertel does not teach or suggest a confidence level for medical treatment or diagnosis protocol, Examiner respectfully disagrees. As discussed above, Examiner observes that these limitations are directed to non-functional descriptive material in so far as the claims do not recite limitations by which the characteristics of the protocol information and evidence level data cause a functional or structural difference in the claimed invention. These limitations have been considered, but not given patentable weight so as to distinguish Applicant's claims from the prior art (see MPEP § 2106.01 for further discussion). Further, Ertel teaches a a confidence level for medical treatment or diagnosis protocol in so far as Ertel teaches data quality information/messages (see, at least, col 10, lines 15-65, col 11, line 45-col 12, line 20, and col 28, lines 35-50). Ertel also teaches that these codes are provided either by peer review (i.e. cases that would be of interest to peer review, see, at least col 10, lines 46-55, note that this teaches being provided by peer review in so far as the quality messages used to identify the cases of interest to the peer review group are generated by the peer-review groups interests to that appropriate files can be identified) or empirical information (see, at least, col 10, lines 15-30, note that data quality

messages are automatically assigned by a computer, thus teaching empirical information since computers must operate on empirical rules, as compared to theoretical concepts).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN FERTIG whose telephone number is (571)270-5131. The examiner can normally be reached on Monday - Friday 8:30am to 5:00pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Trammell can be reached on (571) 272-6712. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B.F./

/Mary Cheung/
Primary Examiner, Art Unit 3694